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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,241	02/27/2004	Bent Formby		4809

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244 Oldwoods Road.  
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EXAMINER

JOHNSON, JERROLD D

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,241	<b>Applicant(s)</b> FORMBY, BENT	
	<b>Examiner</b> Jerrold Johnson	<b>Art Unit</b> 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8-10, 16-18, 22-26, 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 8-10, 16-18, 22-26, 28 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 30, "solution colors" are claimed inferentially. There is not antecedent basis for the solution having a color or multiple colors.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5,8,10,16,17,22-26,28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke US 5,686,112 in view of Hughes, Jr. et al (hereinafter "Hughes") US 6,139,873 and Examiner Official Notice.

Re claim 30, Liedtke discloses a disposable dispensing apparatus for storage and dispensing of a topically applied medicament comprising a blister pack having a

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plurality of wells, wherein the medicament is incorporated within a solution for topical administration and contains a biologically active substance. The wells are arranged and grouped into rows and columns. Additionally, the Examiner takes Official Notice that grouping of wells in medicants of this type are typically grouped to assist the user in the proper use of the medicants.

Leidtke does not explicitly disclose a transparent well, but the Examiner takes Official Notice that transparent wells are the norm in disposable medicant dispensing apparatus so as to allow users to view whether a medicant has been taken or not.

Leidtke further discloses indicia 4, which can be numeric or color, but does not explicitly disclose that the solution has multiple colors that can be seen through the wells.

Hughes in col. 14 lines 37-55 describes colors being added to hormone treatments that, like Leidtke, may be topical (line 54) for the purpose of color-coding (line 38).

Accordingly, it would have been obvious to one of ordinary skill in the art to modify the dispensing apparatus of Leidtke with the teaching of Hughes so as to provide a dispensing apparatus that simplifies the medicant taking regimen.

It further would have been obvious to modify an apparatus for color coded topically applied medicants with transparent wells so that the colors of the color coded medicants can be viewed so as to allow the color coding to provide the benefits inherent in color coding.

Re claim 2, the topical treatments of Leidtke and Hughes would meet this

limitation.

Re claim 3, Leidtke discloses a plurality of rows.

Re claim 4, Leidtke shows the wells being grouped in rows and columns, the wells are inherently capable of being used sequentially as claimed.

Re claim 5, colored solutions as taught are inherently capable of being used to indicate when the dose is to be taken as claimed.

Re claim 8, colored solutions as taught are inherently capable of being used to indicate elements, the stage, etc as claimed.

Re claim 10, this claim is intended use only. Additionally, the claim sets forth the well known varying of doses.

Re claim 16 and 17, these claims are set forth by Leidtke.

Re claim 22, see Leidtke.

Re claim 23, the uneven dose of one of four different varieties of concentration, etc. is well known in hormone replacement treatment.

Re claim 24, the intended use of one per day is well known in hormone replacement treatment.

Re claim 25, the intended use of tailoring the treatments is well known in hormone replacement treatment.

Re claim 26, 28 day treatment periods are well known in hormone replacement treatment.

Re claim 28, Leidtke and Hughes disclose hormones.

Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke in view of Hughes US 6,139,873 and McDaniel US 2002/0120225.

Liedtke does not disclose sequential colors being used in the solution.

Hughes discloses adding colors to hormonal treatments for color coding purposes and also discloses topical ointments in col. 14, lines 34-63. Hughes does not disclose sequential colors.

McDaniel discloses in Fig. 9 and page 6 the use of sequential colors within a multi step process for identification purposes.

It would have been obvious to modify the apparatus of Liedtke with the teachings of Hughes and McDaniel so as to provide a multi-day drug blister pack where the user can easily visually identify the correct daily dose via visual identification through the identification of a color within a color sequence.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liedtke in view of Schaefer DE 198 31 263 A1 (US 6,630,149 is the corresponding US Patent and serves as the English language translation).

Liedtke does not disclose non-aqueous solution medicaments.

Schaefer discloses the combination of aqueous solution medicaments and non-aqueous solution medicaments.

It would have been obvious to package both aqueous solution medicaments and non-aqueous solution medicaments in a single blister pack, as taught by Schaefer, so as to minimize the packaging required, and to minimize the potential that the different

medicaments would be separated.

### Response to Arguments

Applicant's arguments have been addressed within the rejections stated above. Applicant's assertion that color, as set forth in Hughes, is being used as an indicia on the pack is categorically wrong. Note the FD&C dyes mentioned in col. 14. Color coding as set forth by Hughes is clearly in the medicant, not on the pack as Leidtke teaches.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDi



Mickey Yu  
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